K111910 (pg 1/2)

OCT 14 2011

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

In accordance with the Food and Drug Administration Rule to implement provisions of the Safe Medical Devices Act of 1990 and in conformance with 21 CFR 807, this information serves as a Summary of Safety and Effectiveness for the use of the PROFEMUR® Gladiator Hip Stems.

Submitted By:	Wright Medical Technology, Inc. 5677 Airline Rd, Arlington TN, 38002 (800) 238-7188
Date:	September 30, 2011
Contact Person:	Gregory Neal *Regulatory Affairs Specialist II*
Proprietary Name:	Gladiator Hip Stems
Common Name:	Hip Stem
Classification Name and Reference:	21 CFR 888.3330 Hip joint metal/metal semi-constrained, with an uncemented acetabular component prosthesis Class III
Subject Product Code and Panel Code:	Orthopedics/87/KWA, JDL, LPH, LZO, JDI
Predicate Devices Name and Number:	PROFEMUR® Hip System Modular Necks PROFEMUR® Z PROFEMUR® Hip System PROFEMUR® X™ Hip Stem PROFEMUR® TL Hip Stem CORAIL® Hip Prosthesis DYNASTY® BIOFOAM™ Acetabular System 510(k): K100866, K091423, K021346, K012091, K052915, K060358, K953111, K042992, K082924
Predicate Classification and Number:	Orthopedics/87/ KWA, 888.3330

DEVICE INFORMATION

A. Device Description

The Gladiator stems are modular hip stems that couple with modular necks. Design features of the stems are summarized below:

- Cementless stem with proximal cpTi plasma spray coating
  - Available in 10 sizes
  - Manufactured from Ti alloy
- Cemented
  - Available in 5 sizes
  - Manufactured from CoCr alloy
  - Distal centralizers available

The Gladiator Hip Stems were evaluated via mechanical testing; including fatigue, fretting, and distraction evaluation. A review of these results indicates that the Gladiator Hip Stems are equivalent to predicate devices and are capable of withstanding expected *in vivo* loading without failure.

B. Intended Use

The Gladiator Hip Stems are intended for use in uncemented and cemented total hip arthroplasty for reduction or relief of pain and/or improved hip function in skeletally mature patients.

Indications for Use

1. non-inflammatory degenerative joint disease such as osteoarthritis, avascular necrosis, ankylosis, protrusio acetabuli, and painful hip dysplasia;
2. inflammatory degenerative joint disease such as rheumatoid arthritis;
3. correction of functional deformity; and,
4. revision procedures where other treatments or devices have failed

The Gladiator cpTi Plasma Sprayed hip stem is intended for cementless hip arthroplasty.
The Cemented hip stem is intended for cemented hip arthroplasty.

C. Technological Characteristic of the Device

The GLADIATOR® Hip Stems have the same technological characteristics as the predicate device. GLADIATOR® Hip Stems are straight cemented and uncemented hip stems with a modular design. They feature a proximal trapezoidal cross-section and a distal rectangular cross-section. For fixation stability in three planes, the stem has a vertically tapered profile in the frontal and lateral planes. The materials used for the GLADIATOR® Hip Stems are identical to the materials used for the predicate devices.

D. Nonclinical Testing

The GLADIATOR® Hip Stems have been tested in distal and proximal fatigue evaluation per the loading regimen prescribed by ISO 7206-4, -6 and -8.

E. Clinical Testing

Clinical data was not provided for the class III hip stem.

F. Conclusions

The indications for use of the Gladiator Hip Stems are identical to the previously cleared predicate devices. The design features and materials of the subject devices are substantially equivalent to those of the predicate devices. The fundamental scientific technology of the modified devices has not changed relative to the predicate devices. The safety and effectiveness of the Gladiator Hip Stems are adequately supported by the substantial equivalence information, materials information, and analysis data provided within this Premarket Notification.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

OCT 14 2011

Wright Medical Technology, Inc.
% Matt Paul
5677 Airline Rd
Arlington, TN 38002

Re: K111910
Trade/Device Name: Gladiator Hip Stems
Regulation Number: 21 CFR 888.3330
Regulation Name: Hip joint metal/metal semi-constrained, with an uncemented acetabular component prosthesis
Regulatory Class: Class III
Product Code: KWA, JDL, LPH, LZO, JDI
Dated: October 12, 2011
Received: October 13, 2011

Dear Mr. Paul:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin L Keith

for Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K111910(pg 1/1)

Device Name: Gladiator Hip Stems

Indications For Use:

1. non-inflammatory degenerative joint disease such as osteoarthritis, avascular necrosis, ankylosis, protrusio acetabuli, and painful hip dysplasia;
2. inflammatory degenerative joint disease such as rheumatoid arthritis;
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The Gladiator cpTi Plasma Sprayed hip stem is intended for cementless hip arthroplasty.

The Gladiator Cemented hip stem is intended for cemented hip arthroplasty.

Prescription Use __X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for MKM

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K111910